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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,819	01/15/2004	Fred J. Molz IV	MSDI-667/PC860.00	5404
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KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER BLANCO, JAVIER G	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 09/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/757,819

Applicant(s)

MOLZ, FRED J.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 63-90 is/are pending in the application.
- 4a) Of the above claim(s) 4,5 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-15, 17-34, and 63-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 2, 17, 24-27, 32, and 34 in the reply filed on July 20, 2007 is acknowledged.
2. Applicant's cancellation of claims 35-62 in the reply filed on July 20, 2007 is acknowledged.
3. Applicant's addition of claims 63-90 in the reply filed on July 20, 2007 is acknowledged.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 6-15, 19-23, 25-31, 33, 69-72, 75, 76, 85, and 86 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Crozet et al. (US 6,375,683 B1).

Referring to Figures 1-8, Crozet et al. disclose a spinal construct comprising:

- (i) A spinal implant (Figure 8: element 30; Figures 1-7: elements 30a, 30b) extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse dimension and corresponding to a select height of an intervertebral space (see column 4, lines 45-50 and lines 54-67); and
- (ii) An elongate member (Figure 8: element 100 and element 200; Figures 1-7: bearing elements 20a, 20b and intermediate plate 11).

As shown in Figures 1-8 (see column 4, lines 45-50 and lines 54-67), the implant includes a first pair of side surfaces spaced apart and arranged generally opposite one another to define said first transverse dimension, and a second pair of side surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension, wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. Also, the implant has a rectangular transverse cross section, and includes rounded corners to facilitate rotation. The spinal construct further includes an interlock, including at least one aperture (bores 15 and/or bore(s) 34) and at least one projection (screw(s) 40 and nut(s) 50). As an alternative interpretation, the interlock could also be the frictional interaction/engagement between the implant and the elongate member (see column 5, lines 27-33), wherein surfaces 32 and 32' or 33 and 33' are the projections, grooves 12a and 22 or 12b and 22 are the apertures, and screw 40 (or screws 40) is the fastener. An axially facing portion of the implant defines at least two tool-engaging elements (sockets 35) *sized and configured for engagement* with corresponding portions of a manipulation tool (see column 4, lines 58-61). The elongate member defines a pair of arcuate slots (24 and/or 14) positioned diametrically opposite one another relative to the longitudinal axis.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no

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significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

6. Regarding the 102(b) rejection based on Crozet et al. (US 6,375,683 B1), Applicants' arguments filed July 20, 2007 have been fully considered but they are not persuasive.

a. Regarding recently added limitation "*comprising an intervertebral fusion device*", the Applicants argue that dependent claim 17 was not previously rejected by Crozet et al. '683 based on said limitation. The Examiner respectfully disagrees. Claim 17, as originally filed, recites a fusion cage, and positively recites said fusion cage as comprising bone growth promoting material positioned within said fusion cage. Crozet et al. implant is a fusion device (a device that will help on fusing/adhering nearby vertebrae). Said device comprises one opening (35).

b. Regarding recently added limitation "*and a plurality of bone anchors extending transversely from said elongated member*", the Applicants argue that dependent claim 24 was not previously rejected by Crozet et al. '683 based on said limitation. The Examiner respectfully disagrees. Claim 24, as originally filed, recites the elongate member as comprising a plate having first and second end portions, said plate defining at least one opening adjacent each of said first and second end portions for receiving a bone screw therethrough for engaging said plate to the adjacent vertebral bodies. Crozet et al. elongated member comprises bone anchors 26 extending transverse to the longitudinal axis of the elongated member.

c. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

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“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

7. Claims 1-3, 6-12, 23-31, 34, 67-72, 74-77, 84-86, and 88 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dixon et al. (US PG Pub No 2002/0107519 A1).

Referring to Figures 1-10, Dixon et al. disclose a spinal construct comprising:

- (i) A spinal implant (plates 31 and/or dowel 53) extending along a longitudinal axis and having a first transverse dimension and a second transverse dimension greater than said first transverse dimension and corresponding to a select height of an intervertebral space (Figures 4 and 5; see paragraph 0030 and paragraph 0041); and
- (ii) An elongate member (flange 33; flange 33 and tube 34).

As shown in Figures 3a-3d, the implant (plates 31) includes a first pair of side surfaces spaced apart and arranged generally opposite one another to define said first transverse dimension, and a second pair of side surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension, wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. Also, the implant includes a substantially rectangular transverse cross section and rounded corners to facilitate rotation.

Alternatively (as indicated above), dowel 53 is the spinal implant comprising a first pair of side surfaces spaced apart and arranged generally opposite one another to define said first

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transverse dimension (distance of the thread on one surface to the thread on an opposite surface), and a second pair of side surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension (distance of the groove on one surface to the groove on an opposite surface), wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. As clearly seen in Figures 8 and 10, and disclosed in paragraph 0039 and paragraph 0044, the spinal implant is engaged with the elongated member. Dowel 53 may be made from bone, biodegradable material, bioabsorbable material, allograft material, or autograft material, which materials are known for being porous.

The spinal construct further includes an interlock (see Figure 2), including at least one aperture (flange slots 32 or arcuate flanges 46) and at least one projection (an end of the implant is broadly interpreted as projecting). The elongate member comprises top and bottom openings 37 to accept fasteners (screws 36). A tool (see Figure 5) is used to rotate the implant from said first transverse dimension to said second transverse dimension.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

8. Regarding the 102(b) rejection based on Dixon et al. (US PG Pub No 2002/0107519 A1), Applicants' arguments filed July 20, 2007 have been fully considered but they are not persuasive.

a. The Applicants argue that Dixon et al. do not disclose "*an intervertebral device including one or more openings configured to promote fusion with the adjacent vertebral bodies*". As clearly seen in Figures 8 and 10, and disclosed in paragraph 0039 and paragraph 0044, dowel 53 comprises opening 54, grooves between the threads, and/or is porous. Dowel 53 may be made from bone, biodegradable material, bioabsorbable material, allograft material, or autograft material, which materials are known for being porous, therefore meeting the "one or more openings".

b. The Applicants argue that Dixon et al. do not disclose the functional limitation "*rotatable relative to said elongated member*". This functional limitation does not require the implant to be connected/attached to the elongated member, so "relative to said elongated member" could be broadly interpreted as the implant being apart from the elongated member and moving relative to the longitudinal axis of the elongated member. Under any of the two "implant" interpretations (see above), the device of Dixon et al. is "rotatable relative to said elongated member". Further, as clearly seen in Figures 8 and 10, and disclosed in paragraph 0039 and paragraph 0044, the spinal implant is engaged with the elongated member.

c. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

"[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v.*

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Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

9. Claims 1-3, 6-11, 17-19, 21, 23-30, 32, 33, 34, and 63-90 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Jackson (US 7,195,643 B2).

Referring to Figures 1-12, Jackson discloses a spinal construct comprising:

(i) A device comprising a fusion cage (fusion cage 1) *adapted for insertion* into an intervertebral space between an adjacent pair of vertebral bodies, said device extending along a longitudinal axis (50) and defining a primary transverse dimension (from surface 6 to surface 8) and a secondary transverse dimension (from surface 42 to surface 43), said secondary transverse dimension *sized for insertion* into the intervertebral space, said primary transverse dimension sized greater than said secondary transverse dimension and corresponding to a select height of said intervertebral space;

(ii) Further comprising a bone growth promoting material (e.g., bone, which inherently comprises bone morphogenic protein; see column 6, lines 63-65; column 8, lines 43-56; column 9, lines 18-45) positioned within (Figures 1-12: cavity 19; Figure 12: opening 72) said fusion cage *to facilitate fusion* with the adjacent vertebral bodies, wherein a person skilled in the art will be left with the choice of selecting a particular bone growth material as is well known in the art (see column 9, lines 18-45); and

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(iii) An elongate member (rod/plate 59) *sized to span* the intervertebral space and a plurality of bone anchors (55) extending transversely from said elongate member and into engagement with the adjacent vertebral bodies *to establish said select height* of the intervertebral space and *to maintain* said select height as said device is rotated about said longitudinal axis *to align* said primary transverse dimension along said select height *to thereby provide* controlled compression of said device (see column 7, lines 31-51; column 8, lines 1-10 and lines 25-31).

As shown in Figures 1-12, the implant includes a first pair of surfaces spaced apart and arranged generally opposite one another to define said first transverse dimension (from surface 6 to surface 8), and a second pair of surfaces spaced apart and arranged generally opposite one another to define said second transverse dimension (from surface 42 to surface 43), wherein the first transverse dimension is substantially perpendicular to the second transverse dimension. Also, the implant has a rectangular transverse cross section, and includes rounded corners to facilitate rotation. The spinal construct further includes an interlock, wherein the interlock could be the frictional interaction/engagement between the implant and the elongate member and/or vertebral surfaces.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Javier G. Blanco

September 18, 2007

A large, stylized handwritten signature in black ink, consisting of a large 'J' and 'B' intertwined.A handwritten signature in black ink, appearing to read 'D. Willse'.

David H. Willse
Primary Examiner